EXHIBIT 7

Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency

(Draft, March 7, 2003)

Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, Environmental Protection Agency (Draft, March 6, 2003)

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Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, Environmental Protection Agency

I. Purpose and Organization of This Document

The purpose of this document is to provide the Fish and Wildlife Service and the National Marine Fisheries Service with an overview of the Environmental Protection Agency's (EPA) screening level risk assessment process for evaluating potential risk to endangered and threatened species from exposure to pesticides. This screening level risk assessment is conducted by the Office of Pesticide Program's (OPP) Environmental Fate and Effects Division (EFED) in support of the registration/reregistration of pesticides. If EFED's screening level risk assessment indicates a potential risk for endangered and threatened species, its proposed regulatory action and assessment will be forwarded to the Field and External Affairs Division (FEAD) in OPP for further analysis. FEAD, in turn, will conduct a more refined assessment for the individual species potentially at risk and will forward their conclusions to the risk management divisions. This document, however, will focus solely on EFED's screening level risk assessment.

This document, which is organized into eight sections, begins with a description of the purpose and organization of the document (Section I). Sections II and III provide a brief overview of the statutory framework under which OPP operates, OPP's mission and organizational structure, and basic information about the Program's regulations and regulatory processes. Section IV provides an overview of EFED, including procedures, data requirements, and processes to support sound science. Section V includes a glossary of terms, which the reader is encouraged to review before proceeding to the risk assessment process overview in Section VI. The definitions in the glossary will help the reader understand the terms that are unique to OPP and that are used in this document. The last part of the document contains a brief summary of future directions for EFED's risk assessment process (Section VII) along with support documents (Section VIII) that provide a more detailed explanation of some of the topics discussed in this overview document.

II. Statutory Framework

A. Statutory Authority

EPA regulates pesticides under two major federal statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), both amended by the Food Quality Protection Act (FQPA) of 1996. Under FIFRA, pesticides intended for use in the United States must be registered (licensed) by EPA before they may be sold or distributed in commerce. EPA will register a pesticide if scientific data provided by the registrant show that, when used according to label directions, it will not cause unreasonable adverse effects on human health or the environment. (FIFRA defines unreasonable

gap - scientific data from the literature

adverse effects as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide .....) Under FFDCA, the Agency is responsible for setting tolerances (maximum permissible residue levels) for any pesticide used on food or animal feed.

With the passage of the Food Quality Protection Act (FQPA) in 1996, both major pesticide statutes were amended to establish a more consistent, protective regulatory scheme grounded in sound science. FQPA mandated a single, health-based standard for all pesticides in all foods; provided special protections for infants and children; expedited approval of safer pesticides; created incentives for the development and maintenance of effective crop protection tools; and required periodic re-evaluation of pesticide registrations and tolerances to ensure that the scientific data supporting pesticide registrations would remain up-to-date in the future.

For this document, the focus will be on environmental risks, which are mainly regulated under FIFRA.

B. Authority to Require Data

By law, the Agency has the authority to obtain data under three provisions of FIFRA:

- FIFRA 3(c)(1)(D) -- Requires the Agency to establish standards for data requirements to support the registration of a pesticide. These data requirements are set forth in 40 CFR Part 158, but EPA has the broad authority to ask for additional data or waive requirements, as appropriate, for a pesticide. These data requirements are discussed under Section IV of this document.

- FIFRA 3(c)(2)(B) -- Provides the broad authority to require additional data on existing products. These data must be "required to maintain in effect an existing registration of a pesticide". If EPA poses a data requirement under this authority, EPA must allow enough time to design the study and generate data. In addition, EPA must comply with the Paperwork Reduction Act.

- FIFRA Section 6(a)(2) -- Requires that pesticide registrants inform the Agency of any relevant adverse effects information relating to their products, even though it was not formally requested by EPA. Information reportable under this provision includes not only new information derived from scientific studies, but also reports of incidents of adverse effects resulting from the use of pesticide products. (See http://www.epa.gov/epsticides/fifra6a2/ for more information concerning EPA's published guidelines and regulations for Section 6(a)(2)).

C. Definitions and Types of Pesticides

if the CFR acknowledges - why isn't EPA testing for registration?

Based on the Code of Federal Regulations (CFR), pesticides are defined as:

> "Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or dessicant...." (40 CFR 152.3).

Substances that are not included in this definition include, but are not limited to, fertilizers, deodorizers, physical barriers against pests (non-toxicants), or other plant nutrient substances which do not target pest species. Some pesticide products or products containing pesticides may be exempt from requirements of FIFRA, such as those for human drug use only, pesticide treated articles (clothing, paints etc), pheromones used in traps, food preservatives, or natural repellants such as cedar wood.

→ is pesticide defined strictly as active + inerts?

Based on 40 CFR 152.3, an active ingredient and an inert ingredient, respectively, are defined as follows:

> "Any substances (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, dessicant, or defoliant within the meaning of FIFRA section 2(a), except as provided in §174.3 of this chapter."

→ inerts, disinfectants, adjuvants, other actives = mixtures

> "Any substance (or group of structurally similar substances if specified by the Agency), other than active ingredient, which is intentionally included in a pesticide product, except as provided in §174.3 of this chapter."

Many different types of pesticides are available. They may be grouped according to the pests they control, their use pattern, or their chemical class. More often, pesticides are grouped according to the pests they control. The following list provides some examples of the categories of pesticides that are grouped this way:

- Insecticides - kill or prevent the growth of insects. Also includes specific types such as miticides, mosquito larvicides or adulticides;
- Herbicides - kill or control plants, weeds, or grasses;
- Rodenticides - kill or control rats or other rodents;
- Avicides - kill or control damaging bird populations;
- Fungicides - kill or control fungi on food or grain crops;
- Nematicides - kill or control nematodes (microscopic, worm-like organisms that feed on plant roots);
- Fumigants - gaseous pesticides used for insect and fungal control;
- Antimicrobials - kill or control microscopic organisms on external surfaces;
- Plant Growth Regulators - accelerate or retard plant growth rates;
- Insect Growth Regulators - retard insect growth;

- Biopesticides - naturally occurring substances with pesticidal properties, including microbial pesticides, biochemical pesticides and plant pesticides;
- Piscicides - kill or control unwanted or invasive fish populations; and
- Molluscides - kill or control slugs or snails.

Pesticides may also be categorized into the following general use patterns in order to determine registration data requirements: terrestrial, aquatic, greenhouse, forestry, domestic outdoor, and indoor (40 CFR 158). The terrestrial, aquatic, and greenhouse patterns are further divided into food crop and nonfood applications.

Pesticides that have similar chemical structures often have similar toxicological modes of action, as well as comparable fate and transport properties. Such chemicals may be grouped in the same chemical class. Chloronicotinyl compounds (e.g., imidacloprid, nicotine), N-methyl carbamates (e.g., carbaryl, aldicarb), organophosphorus compounds (e.g., chlorpyrifos, diazinon), and pyrethroids (e.g., cyfluthrin, cypermethrin) are just some of the chemical classes that are used as insecticides. Chemical classes with herbicidal action include benzoic acids (e.g., dicamba), chloroacetanilides (e.g., alachlor, metolachlor), chlorophenoxy acids/esters (e.g., 2,4-D, MCPA), imidazolinones (e.g., imazamox, imazapyr), sulfonyl ureas (e.g., bensulfuron-methyl, rimsulfuron), thiocarbamates (e.g., butylate, molinate), and triazines (e.g., atrazine, simazine). Benzimidazoles (e.g., benomyl, thiabendazole), carboxamides (e.g., carboxin, flutolanil), and dithiocarbamates (e.g., maneb, ziram), are a few of the chemical classes that are used as fungicides.

III. Overview of OPP

A. The Mission of OPP

EPA's overarching mission is to protect human health and to safeguard the environment – air, water, and land – upon which life depends. An important component of this goal is the protection of human health and the environment from unreasonable adverse effects resulting from the use of pesticides and to assure that pesticide residues that may occur in food are safe.

OPP's mission is both challenging and complex. OPP regulates the use of all pesticides in the United States and establishes maximum levels for pesticide residues in food, thereby safeguarding the nation's food supply. Pesticides play a role in many aspects of everyday life, from agriculture and greenhouses to lawns, swimming pools, and food service establishments. There are about 20,000 registered pesticide product formulations, containing approximately 675 active ingredients and 1,835 other ingredients. About 470 pesticide active ingredients are used in agriculture, and EPA has established more than 9,000 tolerances (maximum allowable residue limits) for pesticides that may be present in food.

EPA's regulation of pesticides directly or indirectly affects approximately 30 major

pesticide producers, another 100 smaller producers, 2,500 formulators, 29,000 distributors and other retail establishments, 40,000 commercial pest control firms, one million farms, three and a half million farm workers, several million industry and government users, and all households.

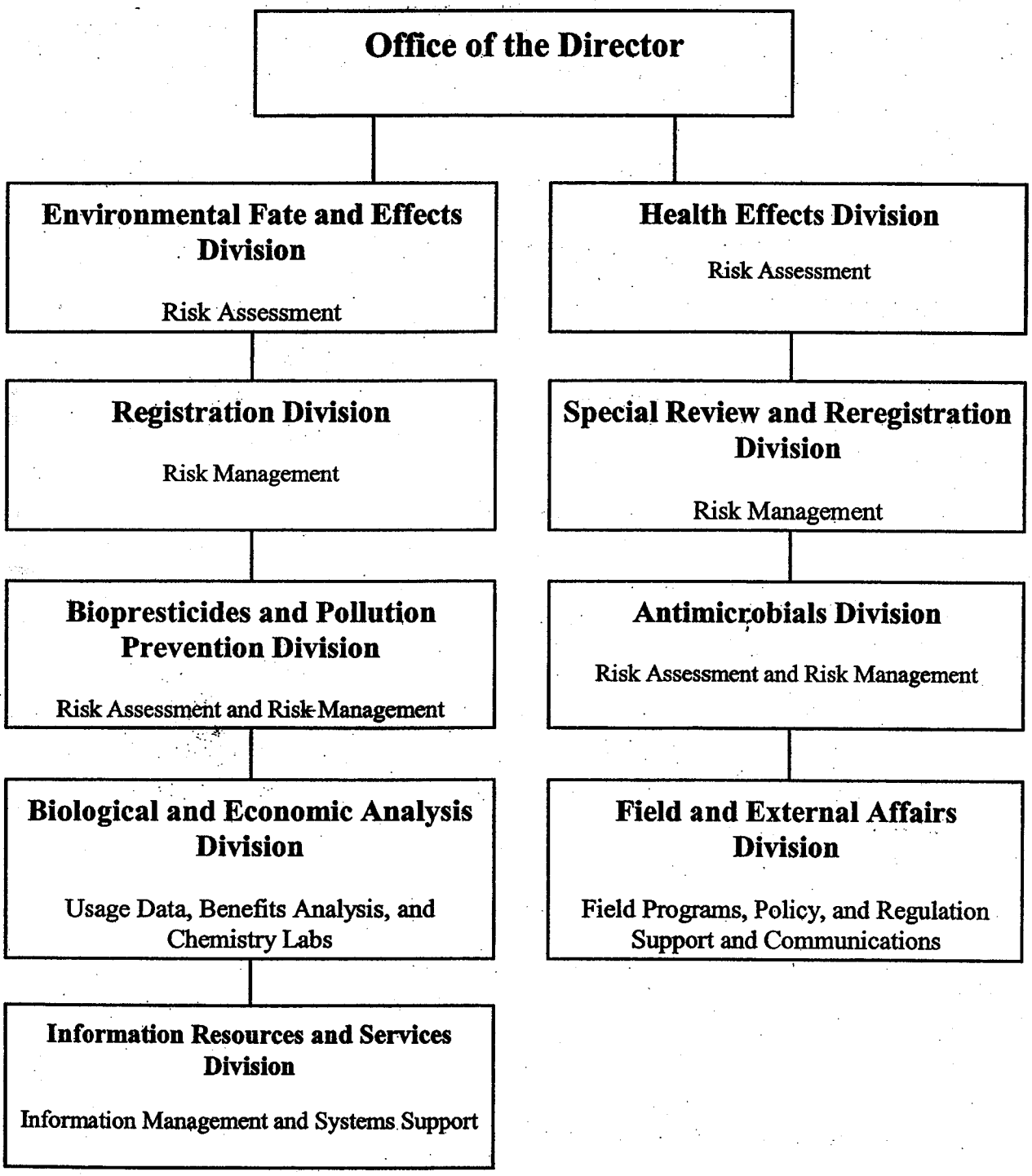
B. Organizational Structure of OPP

OPP is divided into nine divisions and a resource management staff located in the Director's Office. (See Figure 1 below.) Within OPP, approximately 800 people in nine divisions carry out a wide range of activities relating to pesticide regulation and management. In addition, a large number of people in other EPA offices, including EPA regional offices, provide administrative, legal, enforcement, and research support.

It should be noted that in OPP, a distinction is made between the role of the risk assessor and risk manager. Scientists conduct the risk assessment, which uses factual information to quantify the human and ecological effects from the use of a pesticide. Risk managers determine how the pesticide will be regulated. In regulating ecological effects, the regulatory decision will be based on the results of the risk assessment and potential mitigation options, but may also include the integration of social considerations and economic factors (benefits information), and legal requirements. Trade-offs between different regulatory actions are evaluated, and value judgements applied to reach a decisions.

Risk management clearly addresses a variety of considerations that range from scientific to socio-economic considerations. The risk analysis focuses on providing an unbiased evaluation of risk, with assumptions and uncertainties clearly articulated. By clearly defining the pesticide risk assessment process, within the broader risk management framework, the integrity and transparency of the scientific analyses are maintained.

Figure 1: OPP Organizational Structure



1. Science-based Divisions

These divisions focus primarily on conducting the risk and benefit assessments of the pesticides program; they do not perform risk management functions. The results of the science assessments are forwarded to the risk management divisions discussed in the next section. In the case of risk and benefit assessments for endangered and threatened species, the results are forwarded to FEAD .

- **EFED** - Assesses ecological risk and drinking water exposure through state-of-the-science techniques. These assessments are considered in risk management decisions. Drinking water exposure assessments are sent to the Hazard Effects Division to be considered in their human health risk assessments.
- **Health Effects Division (HED)** - Reviews and validates data on pesticide human health effects and characterizes and assesses risks to humans and domestic animals, which are considered in risk management decisions.
- **Biological and Economic Analysis Division (BEAD)** - Assesses pesticide use and benefits information and operates analytical chemistry and antimicrobial testing laboratories.

2. Risk Management Divisions

These divisions focus primarily on the risk management of conventional pesticides, including the registration and reregistration processes.

- **Registration Division (RD)** - Coordinates and manages the licensing of new pesticide active ingredients, new uses of existing pesticide active ingredients, old chemicals, product and label amendments, experimental use permits, tolerances, and emergency exemptions based upon a scientific evaluation of data and other considerations.
- **Special Review and Reregistration Division (SRRD)** - Coordinates and manages the reregistration of pesticides and reassessment of tolerances based upon a scientific evaluation of data and other considerations.

3. Science-based and Risk Management Divisions

In OPP, two divisions perform both risk assessment and risk management functions. It should be noted, however, that the role of risk assessor and risk manager in these divisions are never assumed by the same person. The risk assessment and risk management functions are delineated.

- **Antimicrobials Division (AD)** - Provides full regulatory service for antimicrobial pesticides, including registration and reregistration, risk and benefit assessments, and

review of efficacy data for public health pesticides.

- **Biopesticides and Pollution Prevention Division (BPPD)** - Devoted to biologically-based pesticides and measures that will reduce pesticide risks. BPPD's functions include risk and benefit assessments, risk management, tolerance reassessment, and the Pesticide Environmental Stewardship Program (PESP). PESP is a voluntary partnership between EPA and the pesticide user community to reduce pesticide risk in agricultural and nonagricultural settings.

4. Other Divisions

The remaining two divisions provide unique support functions for OPP.

- **FEAD** - Coordinates OPP's policies and regulatory work, field and international programs. These programs include Certification and Training, Agricultural Worker Protection Program, Endangered Species Protection Program, and others. FEAD also administers region/state/tribal coordination and assistance, legislation and Congressional interaction, and communication and outreach activities.
- **Information Resources and Services Division (IRSD)** - Provides information and computer support for OPP, maintains OPP's Web site, handles the Public Docket, FIFRA section 6(a)(2) issues.

D. Regulatory Processes

OPP reviews many types of registration actions, which are listed below:

1. Section 3 (FIFRA) Registrations

Section 3 of FIFRA authorizes EPA to register new pesticide active ingredients and new uses of existing pesticide active ingredients for use in the United States. In registering pesticides, EPA may place restrictions on the site or crop on which they are used; the amount, frequency and timing of their use; and the storage and disposal practices. Some pesticides may be registered for more limited use in certain states. In addition, States, Tribes and Territories can place further restrictions on pesticides/EPA-registered products used or sold within their own jurisdictions.

For a Section 3 registration action, the pesticide manufacturer submits to EPA a registration application, which includes the following information:

- Required test data;
- Product chemistry;
- Human and environmental data packages;
- Tolerance information, consisting of information about pesticide residues on food
- Proof that the manufacturing process is reliable;

- Labeling information; and
- Occupational data, including directions for use, appropriate warnings, and evidence of meeting all legal and financial obligations.

RD processes the application and tracks it. A project manager is assigned who:

- Completes a detailed review of the application;
- Assigns and coordinates the appropriate scientific review;
- Sets priorities and a timetable;
- Coordinates administrative action; and
- Communicates with the pesticide applicant or registrant concerning the review of his/her application.

RD assigns the scientific review to HED for an evaluation of human health risks, emphasizing sensitive groups such as children and immune-suppressed individuals, and to EFED for evaluating environmental risks, including potential risks to endangered and threatened species. HED compiles all the human health effects and exposure data on the pesticide product into a comprehensive health risk assessment to determine the impact that the pesticide product or active ingredient will have on the human population. At the same time, EFED compiles all the scientific ecological effects and exposure information on the pesticide product into a comprehensive environmental risk assessment to determine potential impacts on the environment. Both the health and environmental risk assessments undergo a process of internal peer review by scientific experts.

After EFED and HED submit their individual risk assessments to the Registration Division, RD reviews the risk assessments and develops potential risk mitigation measures. RD also researches the use of alternative registered pesticides and explores risk management options with the pesticide applicants. Finally, RD makes a registration determination based on the following standards:

- Does the proposed pesticide use meet EPA's standards for human health protection?
- Does the proposed pesticide use meet EPA's standard for worker protection?
- Does the proposed pesticide use meet EPA's standard for protecting the environment?

If the application fails to meet these standards, RD notes the need for more or better data, labeling modifications, and use restrictions, and communicates the deficiencies to the applicant. If the application is approved, EPA may establish a tolerance if the pesticide is intended for use on food and publishes a notice in the Federal Register.

2. Experimental Use Permits (EUPs)

Under FIFRA section 5, EPA may authorize field testing of unregistered pesticides

through an experimental use permit (EUP). The EUP establishes limited conditions for the transportation, application, and disposal of unregistered test products. The granting of an EUP limits the sale and distribution of the test product only between approved participants in the test program, and use of the test product under conditions specified in the EUP. Registrants typically request EUPs to gather large-scale efficacy testing and/or crop-specific residue chemistry data.

any off-target testing?

3. Emergency Exemptions

Section 18 of FIFRA authorizes EPA to allow States to apply a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist. Most requests for emergency exemptions are made by state lead agricultural agencies, although the United States Department of Agriculture (USDA) and United States Department of Interior (USDI) also request exemptions. The process generally takes place as follows:

- Growers in particular regions identify a problem situation that registered pesticides will not alleviate. The growers contact their state lead agency (usually the state department of agriculture) and request that the agency apply to EPA for a Section 18 emergency exemption for a particular use. Requests are most often made for pesticides that have other food uses registered. The state agency evaluates the requests and submits requests to EPA for emergency exemptions they believe are warranted. The uses are requested for a limited period of time (no longer than 1 year), to address the emergency situation only. To be as responsive as possible to the states and growers, EPA attempts to make decisions on the requests within 50 days of receipt.

- During this 50-day time period, EPA must perform a multi-disciplinary risk assessment of the requested use, relying largely on data that have already been reviewed for the pesticide. A dietary risk assessment, an occupational risk assessment, an ecological and environmental risk assessment, which includes endangered species and non-target organisms, and an assessment of the emergency are conducted prior to making a decision. For the past several years, EPA has also evaluated the risk to the most sensitive sub-populations (often infants and children) in its dietary risk assessments. The Agency's evaluation also includes an assessment of the progress toward registration for the use in question.

If the emergency appears valid and the risks are acceptable, EPA approves the emergency exemption request. EPA will deny an exemption request if the pesticide use may cause unreasonable adverse effects to health or the environment, or if emergency criteria are not met. As a matter of course, a state may withdraw an exemption request at any point in the process.

Under FQPA, EPA must establish formal tolerances (maximum allowable residue levels) to cover all pesticide residues in food, even residues resulting from emergency uses. Tolerances established for emergency exemption uses are time-limited to correspond to the use season. In

establishing a tolerance, EPA must make the finding that there is "reasonable certainty that no harm" will result to human health from aggregate and cumulative exposure to the pesticide, as required by the new FQPA health-based standard. Establishment of these tolerances, with their expiration dates, are published in the Federal Register.

If a need is immediate, a state agency may issue a crisis exemption which allows the unregistered use of a pesticide product for 15 days. The state notifies EPA of this action prior to issuing the crisis, and EPA performs a cursory review of the use to ensure there are no concerns.

If concerns are noted, EPA confers with the state, and under extreme cases may not allow a crisis to be declared. If the state follows up the crisis with, or has already submitted, an emergency exemption request, the use may continue under the crisis until the EPA has made a decision on the request. If the state does not also submit an emergency exemption request, EPA must still establish the appropriate tolerance(s) for the crisis use.

4. Special Local Need (SLN) Registrations

Under Section 24(c) of FIFRA, states may register an additional use of a federally registered pesticide product, or a new end use product to meet special local needs as long as there is both a demonstrated "special local need," and a tolerance, exemption from a tolerance, or other clearance under FFDCA. "Special local need" means an existing or imminent pest problem within a state for which the state lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available. EPA reviews these registrations, and may approve or disapprove the state registration. States may not register new active ingredients under Section 24(c).

5. Reregistration Process

Under Section 4 of FIFRA as amended in 1988, EPA is reviewing older pesticides (those initially registered before November 1, 1984) to ensure that they meet current scientific and regulatory standards. This process, called reregistration, considers the human health and ecological effects of pesticides and results in decisions to reduce risks that are of concern. EPA also is reassessing tolerances (pesticide residue limits in food) to ensure that they meet the safety standard established by FQPA. EPA has integrated reregistration and tolerance reassessment to most effectively accomplish the goals of both programs.

as opposed to what?

Through the reregistration program, EPA is reviewing the human health and environmental effects of 612 groups of related pesticide active ingredients. Those that meet today's scientific and regulatory standards may be declared "eligible" for reregistration. To be eligible, a pesticide must have a substantially complete data base and must not cause unreasonable adverse effects to human health and the environment when used according to Agency approved label directions and precautions.

what are exceptions?

In addition, all pesticides with food uses must meet the safety standard of section 408 of the FFDCA, as amended by FQPA. FFDCA as amended by FQPA also requires the reassessment of all existing tolerances and tolerance exemptions within 10 years, to ensure that they meet the safety standard of the new law.

Reducing risks is an important aspect of the reregistration program. In developing reregistration eligibility decisions (REDs), EPA works with stakeholders including pesticide registrants, growers and other pesticide users, environmental and public health interests, the States, USDA and other Federal agencies, and others to develop voluntary measures or regulatory controls needed to effectively reduce risks of concern. Almost every RED includes some measures or modifications to reduce human health and/or ecological risks. The options for such risk reduction are extensive and include measures such as canceling pesticide products or deleting uses; declaring certain uses ineligible or not yet eligible (and then proceeding with follow-up action to cancel the uses or require additional supporting data); phasing out uses; restricting use of products to certified applicators; limiting the amount or frequency of use; improving use directions and precautions; adding more protective clothing and equipment requirements; requiring special packaging or engineering controls; requiring no-treatment buffer zones; requiring spray drift labeling; employing ground water, surface water, or other environmental and ecological safeguards; and other measures.

have these risk reduction measures been validated?

While assessing and mitigating human health risks is a very significant aspect of the reregistration program, assessing and mitigating ecological risks also is an important part of every reregistration review. In developing REDs, the Agency's internal risk management process includes an evaluation of each pesticide's ecological effects by the ECOR Committee, to ensure that ecological risks are fully considered and ecological risk mitigation options are fully vetted. ***(Need to expand to define and discuss ECOR, risks to listed species, and process.)***

what are these? have their efficacy been validated?

6. Registration Review

FIFRA 3(g) specifies that EPA establish procedural regulations for conducting registration review and that the goal of the regulations shall be the Agency review of pesticide registrations on a 15-year cycle. An Advanced Notice of Proposed Rulemaking was issued in 2000, which alerted stakeholders that EPA was beginning to develop the required procedural regulations. It explained EPA's preliminary interpretation of the authorizing legislation, presented EPA's goals in implementing the statutory provisions, presented the Agency's initial concept of how the registration review program might operate, identified several issues that needed to be addressed, and invited public comment. Since that time, OPP has continued to work on designing the program and is working on the proposed rule-making.

what is appropriate to expand data requirements

IV. Overview and Organization of EFED

EFED performs the following functions:

- Reviews, evaluates, and validates data submitted under FIFRA or provided from other sources on the properties and effects of pesticides;
- Assesses and characterizes (1) fate and transport of pesticides in water, soil, and other environmental media; (2) toxicity to wildlife and vegetation; (3) exposure to non-target vegetation, aquatic life, birds, and other wildlife; and (4) effects on endangered species and their habitats as a consequence of proposed or actual pesticide use;
- Characterizes and assesses exposure of the environment to pesticides; including drinking water used for human consumption;
- Characterizes ecological risk from the use of pesticides and the likelihood of effects on aquatic life, wildlife, and plants based on varying pesticide scenarios
- Develops and maintains databases and makes data accessible to the public;
- Develops and advances methods and tools for environmental fate, ecological risk and drinking water assessments;
- Designs and reviews protocols for environmental data collection; and
- Works cooperatively with other government or private entities to gather environmental measurement data.

In conjunction with HED, EFED supports OPP's risk management divisions, RD and SRRD, in the overall risk assessment of pesticides. In addition, EFED provides scientific expertise to other agency programs and Federal agencies on the environmental fate and effects of pesticides and their exposure in various environmental media.

A. EFED Procedures

EFED scientists review and evaluate studies submitted by registrants in support of registration/reregistration of pesticides to determine if they are acceptable. This determination is based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data submitted fulfill Agency requirements. In evaluating experimental design, the scientists consider whether generally accepted methods were used, sufficient numbers of measurements were made to meet Agency standards, and sufficient controls were built into all phases of the experiment. They evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The scientists' review of a study is documented in a Data Evaluation Record (DER), whose formats were harmonized with Canada Pest Management Regulatory Agency's review templates in 2001.

In the DER, studies are categorized as to their usefulness in a risk assessment. While different terms have been used over the years to describe the quality and value of environmental fate and ecological effects studies, there is consistency in the general meaning of the classifications and their application. The three general categories used for classifying scientific studies are Core or Acceptable; Supplemental, Upgradable, or Ancillary; Invalid or Unacceptable. For a more detailed discussion, see Support Document #1.

Studies are also evaluated by contractors, who will generate DERs under formats specified by EFED. These DERs are reviewed by staff scientists within the assigned branch. The branch Work Assignment Manager (WAM) oversees the contractors' performance, and QA/QC procedures are included in the contractors statement of work. The branch WAM contacts the contractors if there are any problems with the reviews or if the review process needs to be changed.

After developing DERs for individual studies, EFED scientists develop disciplinary assessments (fate, water, and hazard assessment), exposure assessments, and risk assessments. These assessments are produced by a team of interdisciplinary scientists and are combined into an integrated science chapter which describes the potential impact of a pesticide on nontarget organisms and the environment. These science chapters are sent to either SRRD or RD and to HED so that the water assessments can be incorporated into the human health risk assessments.

B. Data Requirements

As discussed previously, OPP has the authority, under FIFRA, to request data in support of the registration of a pesticide product. Accordingly, OPP has developed regulations (40 CFR Part 158) which specify the types and amount of information that registrants must routinely submit to EPA to support the registration of pesticide products. Section 158.290 describes the environmental fate data requirements, section 158.490 describes the wildlife and aquatic organisms data requirements, section 158.540 describes the plant protection data requirements, and section 158.590 describes the nontarget insect data requirements.

not under ESA

The data requirements are grouped according to general use pattern(s) and are listed as either required (R) or conditionally required (CR). In most cases, the data listed in Part 158 is sufficient to allow EPA to evaluate a pesticide application. In those cases where the data is not sufficient, EPA can impose additional data requirements. These data requirements are revised from time to time to reflect statutory changes, policy changes and new technology. The data requirements are listed in Section VIII, Support Document #29.

Over the course of conducting a risk assessment, the assessors may note areas where studies are not available that satisfy the core requirements for a particular study. In such cases the risk assessor will evaluate whether conduct of the study or repetition of the study when existing data are not completely satisfactory for regulatory requirement will materially alter the conclusions of the risk assessment. This evaluation considers the nature of the use site for the pesticide, the types of effects already observed from available acceptable data, and the present conclusions of the risk assessment. if the assessors conclude the performance of an additional study will not likely alter the present conclusions of the risk assessment they may indicate the data deficiency to the risk manager but recommend that the study be held in reserve for reconsideration of its necessity should future registrations be considered for the pesticide. The term reserve is used in its literal sense as meaning something set aside for a special purpose.

registration w/ all required da

How can registrations proceed when the missing data were T+E specific address

Should a new use scenario in the future be considered for registration that would likely render the missing information critical to completion of a new risk assessment, then the data requirement could be reconsidered by the risk managers.

To illustrate: a pesticide is proposed for use on bean sprouts at a rate of 1 lb a.i./acre. Evaluation of the data set for this chemical indicates that there is no estuarine/marine invertebrate chronic data available that meets core data requirements. The available estuarine/marine invertebrate chronic study is supplemental and provides a LOEC but not an NOEC. Review of the available acceptable acute and chronic data for freshwater invertebrates and acute data for estuarine/marine invertebrates suggest freshwater and estuarine/marine invertebrates are not appreciably different in terms of acute sensitivity and the relationship between acute and chronic endpoints for freshwater invertebrates re quite similar to the available data for estuarine/marine invertebrates. The risk assessment suggests that the RQs for freshwater invertebrates are far below levels of concern and that RQs for estuarine/marine invertebrates are similarly below levels of concern. Under these conditions of pesticide use it is deemed unlikely that a repeat of the estuarine/marine chronic invertebrate study would generate data that would markedly alter the conclusions of the risk assessment for bean sprout use of the pesticide. However, the risk assessor recognizes that the pesticide might be proposed for uses on other crops in the future, and that these crops may require higher use rates, different use intervals or application methods, or may be situated in regions with higher potentials for runoff than bean sprouts. Recognizing that exposure may go up under other uses and that the margin between RQs and LOCs may be much narrower than for bean sprouts, the risk assessor indicates that the requirement for a repeat of the estuarine/marine invertebrate study should be held in reserve for such future contingencies.

C. Processes to Support Sound Science

Sound scientific assessments are essential and serve as the foundation for regulatory decision-making in OPP. In order to advance the quality and consistency of EPA's ecological risk assessments, the Agency developed guidance for improving the ecological assessment process, risk characterization, and peer review process. EFED follows the Agency guidance and has also developed its own processes for promoting sound scientific assessments.

1. Agency Guidance

a. Guidelines for Ecological Risk Assessments

The Agency's Guidelines for Ecological Risk Assessments (Agency Guidelines, Support Document #7) were issued to advance the quality and consistency of EPA's ecological risk assessments. As a next step in a continuing process of ecological risk guidance development, the guidelines draw from a wide range of source documents including peer-reviewed issue papers and case studies previously developed by EPA's Risk Assessment Forum. EFED has been and will be continuing to advance its assessment processes, using the Agency Guidelines as a guide.

This includes advancements to all three phases of the assessment process, including problem formulation, analysis, and risk characterization.

c. Peer Review Handbook

The Agency's Peer Review Handbook was issued in 1998 as a single, centralized form of implementation guidance for Agency staff and manager. This Handbook builds on an active tradition of peer review at EPA and reflects the Agency's long-standing commitment to peer review.

EFED has actively participated in the peer review process, which is discussed in more detail later in this Section. The Handbook has served as an important guide and has helped to ensure that OPP decisions regarding ecological risk are fully supported by sound and credible science.

2. Tools to Promote Sound Science

EFED uses a variety of tools to ensure that the work performed meets the necessary level of quality and includes, but is not limited to, the following elements: 1) Data Requirements; 2) Pesticide Assessment Guidelines and other guidance documents; and 3) Standard Evaluation Procedures. Each of these elements is described below.

a. Pesticide Assessment Guidelines

EFED has developed Pesticide Assessment Guidelines for assessing the potential impact of pesticides on non-target organisms and the environment. The guidelines describe what data are required to support a registration/reregistration action, test standards that should be used in conducting the studies, specific reporting requirements for the tests, and examples of acceptable protocols, references and other aides to help the registrant in planning and conducting their tests. They include Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms; Subdivision J, Hazard Evaluation: Nontarget Plants; Subdivision L, Hazard Evaluation: Nontarget Insects; and Subdivision N, Chemistry: Environmental Fate (Support Documents #2, #3, #4, #5, respectively.)

After pesticide registrants produce studies in accordance with these guidelines, EFED evaluates the studies to determine their adequacy and validity and to ensure that appropriate quality assurance procedures were followed. In 1991, EFED undertook a study to analyze the factors that most frequently caused studies required for pesticide registration/reregistration to be rejected. After reviewing all the guideline studies, EFED published their analyses. These reports are the1993 "Pesticide Reregistration Rejection Rate Analysis: Environmental Fate" and the 1994 "Pesticide Reregistration Rejection Rate Analysis: Ecological Effects." The information in these reports will allow registrants to minimize rejection of future studies.

b. Standard Evaluation Procedures

EFED has developed Standard Evaluation Procedures (SEPs) or guidance documents for each test which is required to support the registration/reregistration of pesticides. EFED has also developed SEPs which describe the Agency's pesticide risk assessment methods. (Support Document #6 provides a list of SEPS, which are available upon request in hard copy or as a PDF file.) These guidance documents explain the scientific procedures used by EFED to evaluate environmental fate and effects data submitted to the OPP. They have been designed to ensure comprehensive and consistent scientific review of data. Revisions to the SEPs or proposals for new SEPs are discussed and developed within the six EFED Technology Teams followed by review and approval by the Science Policy Panel. After internal approval by the Science Policy Panel and division management, the SEPs are reviewed by an external science peer review group, such as the Scientific Advisory Panel. (The Technology Teams and Science Policy Panel are discussed in later parts of this Section.)

c. Databases

EFED continues to develop, advance, and expand its databases and information systems to support a sound scientific process. These include the Ecotoxicity Database, Ecological Incident Information System, and Environmental Fate Database along with databases that address ground and surface water.

Ecotoxicity Database: Over the last 30 years, pesticide registrants or manufacturers have submitted thousands of ecotoxicity studies to support the registration or approval of their pesticide products. Ecotoxicity studies measure the effects of chemicals on fish, wildlife, plants, and other wild organisms. EFED has reviewed these studies according to criteria outlined in the Standard Evaluation Procedures Manuals and testing methods accepted by the scientific community. After reviewing these studies, EFED scientists have determined if they are acceptable for use in the regulatory process.

In 1991, EPA began electronically summarizing acceptable studies and has now entered over 15,000 summary records for about 680 pesticide active ingredients into a computerized database called the Pesticide Ecotoxicity Database. These summary records include endpoints measurements such as the LD50 (the amount or dose of a chemical which kills 50% of the exposed animals) and the NOEL or No Observed Effect Level (the highest concentration of a chemical in a toxicity test that has no significant adverse effect on the exposed population of test animals).

Although most of the toxicity information in this database was compiled from studies conducted by commercial laboratories, the database also contains acceptable studies conducted by EPA, USDA, and the Fish and Wildlife Service laboratories and published data which meets the Agency's guideline testing requirements.